IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

STELLA S. BENJAMIN, individually and as Administratrix of the Estate of CORNELIUS M. BENJAMIN, Plaintiff, vs. JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON, CO., AND MITSUBISHI TANABE PHARMA CORP., Defendants.	CIVIL ACTION NO.: 3:16-cv-01786-BRM-LHG CIVIL ACTION (Document Filed Electronically) **Return Date: September 6, 2016**

PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANT JANSSEN PHARMACEUTICALS, INC. & JOHNSON & JOHNSON, CO.'S MOTION TO DISMISS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Federal Cases

State Cases

State Statutes

Federal Rules

Federal Regulations

Other Authorities

I. INTRODUCTION

Invokana is a name-brand medication prescribed for the treatment of Type 2 diabetes. Plaintiff Cornelius Benjamin developed kidney damage due to ingestion of Invokana. As a result, his wife, on behalf of decedent Mr. Benjamin, asserts 13 claims against Janssen Pharmaceuticals, Inc. ("Janssen"), Johnson & Johnson ("J&J"), and Mitsubishi Tanabe Pharma Corporation ("Mitsubishi"). Janssen and J&J ("Defendants") have moved to dismiss Plaintiff's complaint. The Court should deny Defendants' motion to dismiss under Federal Rule of Civil Procedure 12(b)(6).

First, Defendants put the Rule 8 plausibility standard on a pedestal equal to that of a claim sounding in fraud under 9(b). As a result of that unfounded supposition, together with a circumscribed reading of Plaintiff's complaint, Defendants cobble together case law to seek dismissal, citing to numerous (off-point) medical *device* cases or *generic* pharmaceutical cases in defense of this *brand-name* pharmaceutical drug suit. As medical devices and generic drugs are subject to different rules than brand-named prescription medications, the cases cited by Defendants are inapplicable here. Applying the correct Rule 8 plausibility standard with on-point case law nets an entirely different result: his claims survive under both New Jersey and New York law.[1] Mr. Benjamin is entitled to punitive damages under either New Jersey or New York law.

Second, Mr. Benjamin's design defect-based claims (Counts 2 and 5–7) are not preempted by federal law. Defendants again cherry-pick from limited case law supporting their sweeping contention that all design defect cases against generic **and brand-name** prescription drug manufacturers would be preempted despite binding Supreme Court precedent to the contrary.

Third, Defendants assert that claims against Johnson & Johnson are preempted because Johnson & Johnson is merely a "holding company" and had no authority to amend the design or labeling for Invokana. This is inaccurate. As demonstrated by judicially-notable materials publicly available from both the FDA and Johnson & Johnson's own website, J&J actively

[1] This court need not, at this juncture reach a choice of law analysis because Plaintiff's claims survive under both states' laws. To the extent that the Court may ultimately believe that any of Plaintiff's claims fail under either states' laws, that is a question for another day. *See* Section III, *infra*.

manages Janssen Pharmaceuticals and even shares research and marketing personnel with Janssen. It was and remains intimately involved in the development and labeling of Invokana. Thus, Plaintiff's claims against Johnson & Johnson are not preempted.

II. BACKGROUND

Mr. Benjamin began using Invokana to treat his diabetes in 2013 and subsequently experienced kidney damage and a stroke. *See* Compl. ¶¶ 4, 8, 28. Plaintiffs allege that Defendants failed to adequately warn of the risk of kidney damage and stroke from ingesting Invokana, along with other injuries that can be caused by the drug, some of which may also result to kidney damage.

But Plaintiff alleges more than the mere use of Invokana in connection with Mr. Benjamin's injuries. Plaintiff alleges that Defendants knew the mechanism of action of the sodium-glucose cotransporter 2 inhibitors and that Invokana's mechanism of action results in severe kidney damage, as well as other injuries. Id. ¶¶ 18-22. Moreover, Defendants were aware of a growing number of Invokana adverse event reports yet did not change the label, or otherwise warn physicians, patients, or the public at large of those dangers. Id. ¶¶ 23-28, 34-37, 39.

III. CHOICE OF LAW

On a motion to dismiss for failure to state a claim, a "defendant bears the burden of showing that no claim has been presented." *Hedges v. United States*, 404 F.3d 744, 750 (3d Cir. 2005). In order for Defendants to successfully dispose of ***any*** of Plaintiff's claims, Defendants bear the burden on showing that his or her claims fail under **both** New York and New Jersey law in their opening brief. Stated another way, because Defendants have failed to make any claim-by-claim arguments required for a choice-of-law analysis -- let alone any discussion of conflict at the outset -- Defendants bear the burden of proving the claims fail under **both** of the set-forth states (New York and New Jersey) for each claim.

In any event, choice of law issues are inappropriate to resolve on a motion to dismiss in the first instance when key factual matters have yet to develop. *See, e.g., Argabright v. Rheem Mfg. Co.*, No. CV 15-5243 (JBS/AMD), 2016 WL 3536621, at *4 (D.N.J. June 28, 2016) (denying a motion to dismiss and simultaneously finding that "the factual record is not full

enough to make a choice of law determination, the Court will postpone the choice of law analysis to a later stage")[2].

IV. LEGAL STANDARD

A plaintiff's pleading requires "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly, 550 U.S. at 570*). To meet the plausibility standard, a plaintiff's allegations must show that defendant's liability is more than "a sheer possibility." *Id.* "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

"The plausibility standard is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* All a Plaintiff must show are facts that tend to "'raise a right to relief above the speculative level[.]'" *Siwulec v. J.M. Adjustment Servs., LLC*, 465 F. App'x 200, 202 (3d Cir. 2012) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555, (2007)). "The issue before the Court is not whether plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence in support of the claims." *Touristic Enters. Co. v. Trane, Inc.*, No. CIVA 09-02732 (SRC), 2009 WL 3818087, at *1 (D.N.J. Nov. 13, 2009) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1420 (3d Cir. 1997)); *see also Phillips v. Cnty. of Allegheny*, 515 F. 3d 224, 234 (3d Cir. 2008) (relying on *Twombly* to hold that to survive a motion to dismiss a complaint must assert "enough facts to raise a reasonable expectation [] discovery will reveal evidence of the necessary element").

The Third Circuit observed, applying *Twombly* and *Iqbal*, that in evaluating the legal sufficiency of a complaint's allegations, a court "accept[s] all factual allegations as true,

[2] *See also Krys v. Aaron*, 106 F. Supp. 3d 472, 481 (D.N.J. 2015) (stating that "the factual inquiry necessary for a choice of law analysis often proves 'inappropriate or impossible' at the motion to dismiss stage 'when little or no discovery has taken place.'" (quoting *Erlandson v. Hartz Mountain Corp.*, 792 F. Supp. 2d 691, 700-01 (D.N.J. 2011) (citation omitted) (also citing additional cases that have determined that a choice-of-law analysis is premature at the motion to dismiss stage); *Snyder v. Farnam Co.*, 792 F. Supp. 2d 712, 721 (D.N.J. 2011) (same); *Harper v. LG Elecs. USA, Inc.*, 595 F. Supp. 2d 486, 491 (D.N.J. 2009) (same).

construe[s] the complaint in the light most favorable to the plaintiff, and determine[s] whether, under any reasonable reading of the complaint, the plaintiff may be entitled to relief." *Phillips*, 515 F. 3d at 233 (quoting *Pinker v. Roche Holdings Ltd.*, 292 F. 3d 361, 374 n.7 (3d Cir. 2002)). "The Court's role is not to determine whether the non-moving party 'will ultimately prevail' but whether that party is 'entitled to offer evidence to support the claims.' *Williams v. Hospice*, No. CV-16-2095-JLL-JAD, 2016 WL 4149987, at *3 (D.N.J. Aug. 3, 2016) (citing *United States ex rel. Wilkins v. United Health Grp., Inc.*, 659 F.3d 295, 302 (3d Cir. 2011)).

The Court's analysis is a context-specific task requiring the court "to draw on its judicial experience and common sense." *Iqbal*, 556 U.S. at 663-64. Moreover, "[i]n deciding a Rule 12(b)(6) motion, a court must consider only the complaint, exhibits attached to the complaint, matters of the public record, as well as undisputedly authentic documents if the complainant's claims are based upon these documents." *Mayer v. Belichick*, 605 F.3d 223, 230 (3d Cir. 2010) (emphasis added).

Additionally, F.R.C.P. Rule 15(a) declares that leave to amend "shall be freely given when justice so requires." "[I]f a complaint is subject to a Rule 12(b)(6) dismissal, a district court must permit a curative amendment unless such an amendment would be inequitable or futile." *Phillips*, 515 F.3d at 245 (citing *Alston v. Parker*, 363 F.3d 229, 235 (3d Cir. 2004)).

As developed below, the Complaint states allegations that give rise to a plausible, not merely possible, entitlement to relief. Plaintiff's allegations are not threadbare recitals of the elements of a cause of action but instead, provide more than sufficient detail for the Defendants to have notice of the claims against them.

V. ARGUMENT

A. Mr. Benjamin's Claims are Sufficiently Pled under Both New York and New Jersey Law

1. Plaintiff Specifies the Extent and Roles of Each Defendant's Wrongdoing

Janssen, as a wholly owned subsidiary of J&J, "marketed, advertised, distributed, and sold" Invokana in addition to "researching, developing, designing, licensing, manufacturing, [and]

supplying" it. Compl. ¶¶ 9, 15. J&J too was directly involved in such "researching, developing, designing, licensing, manufacturing, distributing, supplying, selling[,] marketing, and introducing [of Invokana] into interstate commerce." *Id.* ¶10.

Defendants, however, aver to this Court that J&J is a mere "holding company and did not design, manufacture or sell Invokana." Def. Mot. at 5. Defendants artfully avoid Plaintiff's other allegations (which this Court must accept as true)—that J&J also partook in the "researching … developing, and introducing [of Invokana] into interstate commerce." Compl. ¶ 10. Defendants do not dispute these roles, nor can they.

Defendants emphasize the fact that Janssen is the company that manufactures Invokana in Puerto Rico. Publicly-available documents, judicially noticeable by this Court,[3] accessed from FDA and on J&J's own website, verifies J&J's involvement in the labeling, product launch, and marketing of Invokana. Thus, even absent further discovery, based on the following, there is no question that J&J was involved in the product alleged to cause Mr. Benjamin's injuries.

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[3] For the same reasons that Defendants cite that this Court make take judicial notice of FDA documents, this court may do the same of the FDA documents cited herein. *See* Def. Mot. at 5, n.6; *see also Horne v. Novartis Pharms. Corp*., 541 F. Supp. 2d 768, 777 (W.D.N.C. 2008) ("The Court may take judicial notice of and consider the public record of the FDA . . . .").

Similarly, the Defendants' own website may be judicially noticed. *See O'Toole v. Northrop Grumman Corp*., 499 F.3d 1218 (10th Cir. 2007) (holding that the district court had abused its discretion in refusing to take judicial notice of information from the defendant's website under Rule 201); *see also Hendrickson v. eBay, Inc*., 165 F. Supp. 2d 1082, 1084 (C.D. Cal. 2001) (same); *Under a Foot Plant, Co. v. Exterior Design, Inc.*, No. 6:14-CV-01371-AA, 2015 WL 1401697, at *2 (D. Or. Mar. 24, 2015) (taking judicial notice of an archived version of the defendant's website).

The Court may accept the facts contained on Defendants' own website for the truth of the matter asserted therein. "For purposes of a 12(b)(6) motion to dismiss, a court may take judicial notice of information publicly announced on a party's website, as long as the website's authenticity is not in dispute and 'it is capable of accurate and ready determination.'" *Doron Precision Sys., Inc. v. FAAC, Inc*., 423 F. Supp. 2d 173, 179 n.8 (S.D.N.Y. 2006); *accord Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 167 (S.D.N.Y. 2015) (taking judicial notice of printouts of the defendant's own website because defendant did "not actually dispute the factual material reflected in [them]," but rather "simply . . . prefer[red] that the Court not consider [them]").

J&J posted an online article entitled "Behind the Product Labels."[4] The article details how a third-party label manufacturer is **"**a true partner ***for Johnson & Johnson"*** because the label manufacturer produced Invokana bottle labels in anticipation of FDA approval yet stood at the ready over the Easter holiday to change the label—at ***J&J's*** direction—in the event of "a potential request from the FDA for changes to the label." *Id.* J&J's Director of Trade Accounts is quoted as the person "who manages the relationship between [the third-party label manufacturer] **and Johnson and Johnson** and [who] over saw the product [Invokana's] launch."[5]

J&J's own website also posted (and continues to host) a "Media Fact Sheet" about Invokana, detailing in more generic terms understandable to the public at large about the drug's mechanism of action.[6]

Moreover, even though J&J attempts to establish itself as a mere holding company through its financial filings (*see* Def. Mot. at n. 5), other financial filings on J&J's own website further point to the importance of Invokana to J&J's bottom line. For example, J&J's 2012 Annual report exclaimed that "**We [J&J]** have an exciting and late-stage pipeline of differentiated medicines. New Drug Applications are presently under review in the United States and in the European Union seeking approval for INVOKANA* (canagliflozin), **our [J&J's]** first pharmaceutical treatment for patients with type 2 diabetes."[7] Thus, to the extent J&J attempts to shield itself from liability, by creating a set of nested Russian dolls, J&J is nevertheless at the top of the stack and directly involved, understandably, in the affairs of its underlings.[8] To wit, J&J's 2015 Annual Report states that:

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[4] Exhibit A, Behind the Product Labels, *available at:* https://www.jnj.com/sites/default/files/pdf/JJ%20Diversity%20--%20National%20Label%20and%20Cardinal%20--%2012-23-14.pdf .

[5] *Id* (emphasis added).

[6] Exhibit B, Media Fact Sheet, *available at*: https://www.jnj.com/sites/default/files/pdf/Janssen_INVOKANA%20FactSheet.pdf .

[7] Exhibit C, J&J's 2012 Annual Report at 7, *available at* https://www.jnj.com/sites/default/files/pdf/JNJ2012annualreport.pdf (emphasis added).

[8] Exhibit D, *see* 2015 First Quarter Report of Drug Quarter-over-Quarter sales, *available at* http://www.jnj.com/sites/default/files/pdf/Johnson-Johnson-First-Quarter-2015-Financial-Charts.pdf (listing Invokana).

> The **Executive Committee of Johnson & Johnson is the principal management group** responsible for the strategic operations and allocation of the resources of the Company. This Committee **oversees and coordinates the activities of the Company's three business segments**: Consumer, **Pharmaceutical** and Medical Devices. Within the strategic parameters provided by the Committee, senior management groups at U.S. and international operating companies are each responsible for their own strategic plans and the day-to-day operations of those companies.[9]

J&J describes Invokana as one of the products in its Pharmaceutical segment in its 2015 Annual Report.[10]

Indeed, J&J was involved with Invokana from its initial NDA application. Administrative documents & correspondence for the drug approval package for Invokana establishes J&J's role in the submission of Invokana for the FDA's approval.[11] As part of the NDA application, all FDA investigators had to reveal any financial conflicts of interest. For Invokana, a minimum of thirteen FDA investigators received (and were forced to disclose) various consulting fees ***from J&J*** (not Janssen).[12]

Moreover, Brandon Porter is listed as the Associate Director, Regulatory Affairs, for Janssen Research & Development on the NDA-related correspondence. Brandon Porter, however, wears two hats. He was simultaneously (and remains to be) the Associate Director of Global Regulatory Affairs *for J&J* and, while at J&J, was a "[m]ember of the canagliflozin regulatory team that gained FDA approval of Invokana."[13] Similarly, Leslie Schaefer, a consumer brand director at *J&J*, is the director of marketing for Invokana.[14]

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[9] Exhibit E, J&J 2015 Annual Report, *available at* http://files.shareholder.com/downloads/JNJ/1709744668x0x881109/474857DD-8E67-43B1-BB38-0A9712D93545/2015_annual_report_.pdf, at 1 (emphasis added).
[10] *Id.* at 2.
[11] All FDA drug approval package documents are *available at*: https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000TOC.cfm.
[12]Exhibit F, FDA Medical Reviews at 23, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000MedR.pdf.
[13] Exhibit G, FDA Administrative Documents & Correspondence at 88, *available at* https://www.accessdata.fda.gov/drugsatfda_docs/nda/2013/204042Orig1s000Admincorres.pdf; *see also* Exhibit H, LinkedIn, Brandon Porter, *available at:* https://www.linkedin.com/in/brandon-porter-3aa46a.
[14] Exhibit I, LinkedIn, Leslie Schaefer, *available at:* https://www.linkedin.com/in/leslieschaefer66bb744.

In sum, Janssen and J&J are not haphazardly 'lumped together.' Johnson & Johnson has a special role on the development and marketing of Invokana in its supervision of Janssen's business.[15] *See BK Trucking Co. v. PACCAR, Inc.*, No. CV 15-2282 (JBS/AMD), 2016 WL 3566723, at *6 (D.N.J. June 30, 2016) (naming defendants together in one action was allowed because "Plaintiffs have alleged that all defects requiring repair [when the specific] component systems is uniquely within Defendants' control. The Court cannot expect Plaintiffs to provide more specificity about the [component] without the benefit of discovery.").

2. Mrs. Benjamin's claims on behalf of her deceased husband are plausibly pled under New York law

As explained below, Mrs. Benjamin's claims are plausibly pled under New York law. To recover for any strict products liability theory, under New York law,

> a plaintiff must show [1] that the defect was a "substantial factor" in causing his injuries; … [2] the product is not reasonably safe as marketed; [3] the product was used for a normal purpose; [4] that the plaintiff, by the exercise of reasonable care would not have both discovered the defect and apprehended its danger; and [5] that the plaintiff would not have otherwise avoided the injury by the exercise of ordinary care.

Derienzo v. Trek Bicycle Corp., 376 F. Supp. 2d 537, 560 (S.D.N.Y. 2005)

Mrs. Benjamin has satisfied these preliminary elements for every form of her late husbands' product liability claims (manufacturing defect, failure to warn, and design defect). *First*, Mr. Benjamin was injured, and those injuries were cause – in large part – due tto the product defects. Compl. ¶¶4, 33, 35, 41, and 45(a) ("This conduct and the product defects complained of herein were substantial factors in bringing about and exacerbating Plaintiff's Decedent's injuries."). *Second*, Plaintiffs pled that Invokana is unreasonably dangerous. *See* Compl. ¶¶19-24

[15] For example, many of the top leadership of J&J wear two hats and sit on leadership team of Janssen as well. As a few examples, Joaquin Duato is the Executive Vice President and Worldwide Chairman, Pharmaceuticals for Johnson & Johnson, but also is listed as part of Janssen's leadership. *See* "Our Leadership, Janssen", *available at* http://www.janssen.com/about/our-leadership. The same is true for Paul Stoffels, Chief Scientific Officer, Johnson & Johnson and Worldwide Chairman, Pharmaceuticals; Dr. William Hait, Global Head, Research & Development;
Patrick Verheyen, Global Head of Business Development; and Linda Fedow, Global Lead, Pharmaceuticals Communication & Public Affairs. *Id.*

(explaining the increased dangers of SGLT2 diabetes drugs over non-SGLT2 drugs—including and especially Invokana—in light of mounting FDA adverse event reports). *Third*, the Invokana prescribed and consumed by Mr. Benjamin was used for a normal purpose. Compl. ¶29. *Fourth*, Mr. Benjamin could not have discovered any defect in the Invokana he consumed, even through [*fifth*] the use of ordinary care. Compl. ¶56.

a. Manufacturing Defect (Count 1) is sufficiently pled

In addition to the preliminary product liability elements discussed above, a manufacturing defect claim under New York law is an allegation that "[1] a consumer may reasonably expect a product to be made in accordance with the manufacturer's standards and expect to be compensated for injuries resulting from the manufacturer's failure to meet them. [2] The product is reasonably held defective because the manufacturer has not made the product as it intended." *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 270, 662 N.E.2d 730, 743 (N.Y. 1995)

Specifically, Mrs. Benjamin alleges of behalf of her deceased husband that the Invokana he consumed was not made in accordance with Defendants' design because "it deviated from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." Compl. ¶46. But, as to the Invokana that reached Mr. Benjamin, it did not meet his reasonable expectations because it did not reach him in conformance with those standards. Compl. ¶45(a), (c).

Other courts in New York have allowed such claims to proceed to discovery (post-*Twombly-Iqbal*) to establish such a claim in New York. For example, in *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170 (N.D.N.Y. 2014), a manufacturing defect claim regarding failed implantable heart defibrillator lead wires survived a motion to dismiss because the "[l]eads were 'in general' prone to manufacturing defects." *Id.* at 182 (citing to "factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged"); *see also* Compl. ¶¶19-24 (citing the dangers of Invokana, in general).

Defendants confuse the Rule 9 heightened particularity pleading standard applicable to fraud-based claims for Rule 8-based claims, like this one (subject to "plausibility"). Plaintiffs need

not show, at this stage, "how" J&J and Janssen's manufacturing defect caused his injuries and "how" the Invokana pills consumed by Mr. Benjamin were different than its intended design. Def Mot. at 7. To require such facts at this stage would be akin to requiring an expert report filed with the complaint. No holding has ever gone so far.

b. Design Defect (Count 2) is well pled and not barred by comment k

In addition to the preliminary product liability elements discussed above, a design defect claim under New York law is an allegation that a "product is one which, at the time it leaves the seller's hands, [1] is in a condition not reasonably contemplated by the ultimate consumer and [2] is unreasonably dangerous for its intended use; that is one [3] whose utility does not outweigh the danger inherent in its introduction into the stream of commerce". *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102, 107 (N.Y. 1983) (*citing Robinson v. Reed-Prentice Div. of Package Mach. Co*., 49 N.Y.2d 471, 479 (N.Y. 1980)). Plaintiffs have so alleged.

Specifically, Mrs. Benjamin alleges of behalf of her deceased husband that the Invokana he consumed was in an unreasonably dangerous condition because its "design and formulation, ma[de] the use of INVOKANA more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes." Compl. ¶50(b). And the" harmful side effects [of Invokana] that outweighed any potential utility" to him. Compl. ¶50(e).

Ultimately, it is "**for the jury** to decide whether a product was not reasonably safe in light of all the evidence presented." *Voss v. Black & Decker Mfg. Co*., 59 N.Y.2d at 108 (citing cases) (emphasis added).

Because design defect claims are complicated, "it must be remembered that the products liability jury likely has gone through weeks or months of expert testimony on such complex questions as modification costs, alternatives, utility of the product. Frank J. Vandall, "*Design Defect" in Products Liability: Rethinking Negligence and Strict Liability*, 43 OHIO ST. L.J. 61, 86 (1982) (cited by *Voss v. Black & Decker Mfg. Co*., 59 N.Y.2d 102 at 109).

Again, Defendants confuse the Rule 9 heightened particularity pleading standard

applicable to fraud-based claims for Rule 8-based claims. Plaintiff need not support the complaint with expert testimony as to complicated matters – matters reserved for an expert, at this stage of the litigation. According to defendants, Plaintiff must present – in the complaint –

an expert report on how SGLT2 inhibitors, and Invokana specifically, increase the risk of kidney damage. It is unclear how such a presentation would be done absent an expert report. So long as the litigation proceeds and Plaintiff's expert's theory is viable, it is "for the jury" to decide whether J&J and Janssen's design was reasonable under a risk-utility balancing test after the consideration of expert testimony. Plaintiffs need not prove the case in the complaint.

Furthermore, the Defendants' citation to *McDowell v. Eli Lilly & Co.*, 58 F. Supp. 3d 391, 410 (S.D.N.Y. 2014) for the proposition that comment k to the Section 402A of the Restatement (Second) of Torts bars a design defect claim is misplaced. As cited by *McDowell* (and Defendants), the predicate case, *Martin v. Hacker*, 83 N.Y.2d 1 (N.Y. 1993), expressly ***limits*** comment k: "comment k defense is unavailable for products negligently manufactured, negligently distributed or unaccompanied by proper warnings." *Id.* at 8. In other words, unless and until there is a factual determination that the Invokana warnings are adequate, any and all other claims remain viable.

c. Failure-to-Warn (Count 3) is sufficiently pled

"It is well-settled that a manufacturer has a duty to warn (1)"against latent dangers resulting from foreseeable uses of its product of which it knew or should have known, and (2) of the danger of unintended uses of a product provided these uses are reasonably foreseeable. *Hollman v. Taser Int'l Inc.*, 928 F. Supp. 2d 657, 673 (E.D.N.Y. 2013) (citing cases, internal quotations omitted).

"[T]he New York Court of Appeals has described the standard for evaluating failure to warn liability as 'intensely fact-specific, including but not limited to such issues as feasibility and difficulty of issuing warnings in the circumstances; obviousness of the risk from actual use of the product; knowledge of the particular product user; and proximate cause.'" *Id.* (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 243 (N.Y. 1998)).

Given this fact-intensive inquiry, as the Second Circuit has emphasized, "'[t]he adequacy of the instruction or warning is generally a question of fact to be determined at trial and is not ordinarily susceptible to the drastic remedy of summary judgment.'" *Urena v. Biro Mfg. Co.*, 114 F.3d 359, 366 (2d Cir.1997).

Plaintiffs' failure to warn claim is simple: Mr. Benjamin suffered kidney damage and a stroke. Compl. ¶4. Plaintiffs claim that J&J and Janssen failed to warn about the risks of developing kidney damage and strokes. Compl. ¶54. There is no disconnect between the failure to warn claim and the injuries Mr. Benjamin suffered as Defendants contend. Def. Mot. at 10-11.

Defendants' make the specious argument that a statement in the 2013-version of the Invokana label that "[r]enal function abnormalities [that] can occur" serves as an adequate warning for the kidney damage and stroke suffered by Mr. Benjamin. While Plaintiffs believe this argument stretches the limits of the imagination, the adequacy of this purported warning should be a factual determination by the jury.

Notably, Defendants fail to acknowledge that in May of this year, the FDA required Defendants to *strengthen* the warnings for Invokana. Specifically, the FDA requested new precautions under two of the six safety labeling sections for Invokana.[16] Among those changes was an added section under "WARNINGS AND PRECAUTIONS" for "Acute Kidney Injury and Impairment in Renal Function," including "**postmarketing reports** of acute kidney injury, some requiring hospitalization and dialysis, in patients receiving INVOKANA".[17] The same revised warnings included the fact that doctors should "consider factors that may predispose patients to acute kidney injury including hypovolemia, chronic renal insufficiency, congestive heart failure and concomitant medications." *Id.*

Further, in June of this year, FDA released on over-arching "Safety Announcement"

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[16] *See* Exhibit K, FDA May 2016, Drug Safety Labeling Changes, *available at*: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm505586.htm.

[17] *See* Exhibit L, FDA Invokana warning changes over Time, *available at:* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).

applicable to Invokana.[18] These warnings stated that patients should be assessed periodically for kidney function. These warnings too were not previously disclosed or encompassed in the warnings at the time of Plaintiffs' consumption.

The warnings in effect at the time of Mr. Benjamin's consumption in 2013 instead contained cryptic warnings about creatinine and "[r]enal function abnormalities [that] can occur" pale in comparison to known "Acute Kidney Injury and Impairment" occurring in "postmarketing reports" that required "hospitalization and dialysis." Similarly, the recommendation for routine kidney screening appears nowhere in the version of the warnings in effect at the time of Mr. Benjamin's consumption.[19]

Defendants also brush aside the fact that the label in effect at the time of Mr. Benjamin's 2013 consumption and even that the current label lacks any mention of stroke – instead merely claiming a lack of "facts" linking Invokana to strokes.[20] But as this Court can judicially notice what information was available to the scientific community – and Defendants specifically, about the risk of strokes associated with Invokana prior to Plaintiff's consumption. Concerns regarding Invokana's cardiovascular safety were first raised on January 10, 2013, little more than 2 months ***prior*** to the drug's approval (and years before Mrs. Humphries' first consumption of Invokana). In a meeting of the FDA's Endocrinologic and Metabolic Drugs Advisory Committee ("EMDCA"), Dr. Sidney Wolfe voiced his reservations over a series of troubling clinical trials. Wolfe, founder of the Health Research Group, noted abnormal increases in "hemoconcentration,"

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[18] *See* Exhibit M, Invokana Safety Announcement, *available at* http://www.fda.gov/downloads/Drugs/DrugSafety/UCM506772.pdf and Exhibit N http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm506554.htm (similar).

[19] *Compare* Exhibit J, 2013 Invokana warnings, *available at* http://www.accessdata.fda.gov/drugsatfda_dsssocs/label/2013/204042s000lbl.pdf *to* Exhibit O, Revised May 2016 Invokana Warnings, *available at:* https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/204042s011lbl.pdf (strengthening kidney damage warnings and still lacking any stroke warning).

[20] *See* Exhibit K, FDA May 2016, Drug Safety Labeling Changes, *available at*: http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm505586.htm; *see also* Exhibit L, FDA Invokana warning changes over Time, *available at:* http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm400577.htm (emphasis added).

the balance of red blood cells to plasma, in patients taking Invokana. SGLT2 inhibitors like Invokana increase urine production in an attempt to flush blood glucose, at dangerously high levels in type 2 diabetes patients, from the body. But increases in urination can also be accompanied by increases in "hematocrit," the concentration of red blood cells relative to other fluids. The blood literally becomes thicker, increasing the risk of blood clot formation, heart attack ***and stroke***.[21]

In any event, the fact that Defendants' only serious support for the dismissal of Plaintiffs' failure-to-warn claim is to quibble about the strength (or lack thereof) of the 2013- of the warnings versus the present warnings speaks volumes. These are questions of fact for a jury, not to be resolved as a matter of law. *Urena v. Biro Mfg. Co.*, 114 F.3d at 366.

d. Warranty Claims (Counts 4, 5, and 7)

1. Express Warranty

Though Defendants rightly point to N.Y. U.C.C. § 2-313.as the applicable UCC section on express warranty, they, again, delete pertinent text in order to make their case for dismissal more compelling. An express warranty is formed under New York law when there is "**[a]ny** affirmation of fact or promise made by the seller to the buyer which **relates to the goods** and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise." *Id.* at § 36–2–313(1)(a) (emphasis added). An express warranty remains even if no "formal words such as 'warrant' or 'guarantee'" are used. *Id.* at § 2-313(2).

Here, it is undisputed (or, at a minimum, plausibly alleged in the complaint or through judicially-noticeable facts discussed above) that: 1) Invokana was safe and fit for its intended

[21] *See* FDA's Endocrinologic and Metabolic Drugs Advisory Committee Transcript, January 10, 2013, *available at:* http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/EndocrinologicandMetabolicDrugsAdvisoryCommittee/UCM347614.pdf ; *see also* Foushee, J. A., N. H. Goodbar, J. L. Kelly, and S. L. Clarke. 2014, *Cerebrovascular Accident In A High-Risk Patient During The Early Initiation Phase With Canagliflozin,* Annals Of Pharmacotherapy 48 (8): 1066-1069. SAGE Publications. doi:10.1177/1060028014529412, *available at* http://aop.sagepub.com/content/48/8/1066.short.

purposes through Defendant's statements as of Mr. Benjamin's ingestion in 2013,[22] and 2) that the description of Invokana was not safe because it has serious side effects, namely the one suffered by Mr. Benjamin: kidney damage.[23] Moreover, even if such statements were made to Mr. Benjamin's doctor (and not to him directly), New York recognizes that such statements of safety may be relayed "indirectly." N.Y. U.C.C. § § 2-313(2).

2. Implied Warranty

N.Y. U.C.C. Law § 2-315 provides that "[w]here the seller at the time of contracting has reason to know any particular purpose for which the goods are required and that the buyer is relying on the seller's skill or judgment to select or furnish suitable goods, there is unless excluded or modified under the next section an implied warranty that the goods shall be fit for such purpose."

Defendants' only basis for the dismissal of Plaintiff's implied warranty claim is that her products liability claims fail. For the reasons discussed above, they do not, and hence the implied warranty claim does not fail either. *See* Sections V.A.2.a.-c.

Moreover, Mr. Benjamin has made the requisite allegations. He alleges that he consumed Invokana pills for the purpose for which Defendants intended: long term treatment of his diabetes. Compl. ¶¶ 28-29. He alleges that Defendants knew of the use for which Invokana was intended (treatment of diabetes). Compl. ¶¶ 95, 97. And Plaintiff alleges that Defendants were aware that consumers, including Mr. Benjamin, would use Invokana for treatment of type 2 diabetes (a life-long disease) and other purposes such as weight loss and reduced blood pressure. Compl. ¶¶ 96-98, 103.

e. Negligence-based Claims (Counts 6 and 9)

Defendants merely argue that because Plaintiff's product-liability-based claims must fail (Count 1 [Manufacturing Defect], 2 [Design Defect], and 3 [Failure-to-Warn]), Plaintiff's

[22] Compl. ¶66; *see also* Exhibit P, Defendants' Invokana website as of June 13, 2014, *available at* https://web.archive.org/web/20140613010318/http://www.invokana.com/about-invokana/what-is-invokana (stating that "It's the first of a new kind of prescription medicine that's proven to significantly lower blood sugar (A1C)", but containing ***no*** warnings under "IMPORTANT SAFETY INFORMATION" as to renal/kidney damage or strokes).
[23] *See id.*; *see also* Compl. ¶67.

negligence-based claims (Counts 6 & 9) must fail too. For the same reasons discussed above, those claims are plausibly pled and survive. Also, Defendants are wrong to suggest the Plaintiff failed to plead proximate cause in the complaint. Def. Mot. at 15. Plaintiff did. Compl. ¶89.

f. Fraud-based claims (Counts 8–11)

> To maintain an action based on fraudulent representations, whether it be for the rescission of a contract or, as here, in tort for damages, it is sufficient to show that the defendant knowingly uttered a falsehood intending to deprive the plaintiff of a benefit and that the plaintiff was thereby deceived and damaged."

Channel Master Corp. v. Aluminum Limited Sales, Inc., 4 N.Y.2d 403,406-407 (N.Y. 1958).

Defendants do not contest Plaintiff's causation or losses allegations. Instead, Defendants only claim that Plaintiff's "who, what, when, where, and why" claims are insufficient. Def. Mot. at 15. Defendants' chief complaint is that Plaintiff's failed to point to – among thousands of such examples – marketing materials about Invokana contained material facts about safety. Def. Mot. at 15, n. 17. But the court may consider all of the materials that Plaintiff has already pointed to as judicially noticeable for this reason – for the same reason that Defendants have pointed to their external materials for consideration. *See* Section V.A.1. Each one of those (specifically-dated) statements made by each of the Defendants (or in concert) list who made them, and how they made them (in which medium). *See id.* The why is simple: "sales and profits at the expense of the health and safety of the public." Compl. ¶173.

For example, Defendants' 2013 label, attached as Exhibit J, omits material safety information about Invokana. "An allegation of fraudulent concealment satisfies the particularity requirement if it [1:] alleges the facts a defendant, [2:] who was under the duty to disclose, [and 3:] [what the document] failed to reveal." *Fireman's Fund Ins. Co. v. Allied Programs Corp*., No. 92 CIV. 7505 (CSH), 1993 WL 481344, at *9 (S.D.N.Y. Nov. 17, 1993) (citing *U. S. v. International Brotherhood of Teamsters*, 708 F. Supp. 1388, 1397 (S.D.N.Y. 1989)). Such "a duty to disclose arises 'where one party's superior knowledge of essential facts renders a transaction without disclosure inherently unfair.'" *Swesky v. Dreyer and Traub*, 643 N.Y.S. 2d 33, 57 (N.Y. 1996) (citing cases). Here, Defendants are clearly the party with the superior knowledge about the

risks and side effects of Invokana, and hence owed a duty to disclose all side effects in the 2013 label.

Who:	Janssen and J&J
What:	Defendants "omitted important information about the safety and quality of INVOKANA in the documents and marketing materials Defendants provided to physicians and the general public." Compl. ¶138(b). Namely, nowhere in 2013 label do the Defendants disclose the risks of kidney damage to the same extent as the 2016 label, which, among other things, reported "Acute Kidney Injury and Impairment" that required "hospitalization and dialysis." Moreover, at ***no point*** have the Defendants ever revealed the risks of stroke to physicians or the public.
When:	March 2013 (date on page 41 of Ex. J)
Where:	In product boxes, disseminated to treating doctors and to the public at large.
How:	By prescribing doctors and public at large as to the relative safety of Invokana when compared to other similar diabetic medications. *See also* Compl. ¶¶116, 120-123, 137. 150.
Why:	"[S]ales and profits at the expense of the health and safety of the public." Compl. ¶173.

3. There is No Basis for Striking any of Plaintiff's New Jersey Claims

a. It is too early to determine if Plaintiff's implied warranty, negligence-based, and fraud-based claims (Counts 5–11) are subsumed by the New Jersey Product Liability Act

Although the Court may determine that certain claims are subsumed by the NJPLA at a later time, it is premature to make this determination at this phase absent a choice of law analysis. Defendants have made no meaningful effort to do so and Plaintiff agrees that on a motion to dismiss, it is inappropriate to do so. [24]

b. The manufacturing defect (Count 1) is plausibly pled

Under New Jersey law, a manufacturing defect is a deviation "from the design specifications, formulae, or performance standards of the manufacturer or from otherwise identical units manufactured to the same manufacturing specifications or formulae." *Myrlak v. Port Authority of N.Y. and N.J.*, 157 N.J. 84, 96 (1999) (quoting N.J.S.A. 2A:58C–2a). It occurs when the "product comes off the production line in a substandard condition based on the manufacturer's own standards or identical units that were made in accordance with the manufacturing

[24] *See* Section III (discussing that is premature to make a finding on a choice of law on a motion to dismiss); *see also ADP, LLC v. Bakshi*, No. CV 15-8385 (CCC), 2016 WL 1223557, at *6 (D.N.J. Mar. 29, 2016) ("[D]isputes require discovery and further exploration before a proper choice of law analysis can be performed.")

specifications." As discussed, *see* Section V.A.2.a, Plaintiff has so alleged. Compl. ¶¶46-47.

Importantly, "[t]he Supreme Court of New Jersey has held that the plaintiff may show the [manufacturing] defect through expert testimony or circumstantial evidence." *Ebenhoech v. Koppers Indus., Inc.*, 239 F. Supp. 2d 455, 472 (D.N.J. 2002) (citing *Myrlak*, 157 N.J. at 97). In such a scenario, "proof of proper use, handling, or operation of the product and the nature of the malfunction, may be enough to satisfy the requirement that something was wrong with it. Further, a defective condition can also be proven by the testimony of an expert." *Ebenhoech v. Koppers* Indus., Inc., 239 F. Supp. 2d 455, 472 (D.N.J. 2002). But Defendants' handling and packaging of Invokana is necessarily only in the knowledge of the defendants that discovery will reveal. Thus it is appropriate to withhold dismissal of this claim under New Jersey law given the broad scope of a manufacturing defect claim's proof.[25]

c. The design defect (Count 2) is plausibly pled

Defendants insist that plaintiff must show a reasonable alternative design and "facts" to support that a reasonable alternative design is feasible. Under New Jersey law,

> "[a] plaintiff must prove either that the product's risks outweighed its utility or that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm. Plaintiffs who assert that the product could have been designed more safely must prove under a risk-utility analysis the existence of an alternative design that is both practical and feasible."

Schraeder v. Demilec (USA) LLC, No. CIV. 12-6074 FSH, 2013 WL 5770670, at *2 (D.N.J. Oct. 22, 2013) (citing *Lewis v. Am. Cyanamid Co.*, 155 N.J. 544, 570–71 (NJ 1998)).

These elements of proof at trial, however, are not required to be proven at the pleading stage. An alternative design need not be pled because "it is not required that the Plaintiffs always plead a reasonable alternative design." *Id.* "A plaintiff must prove ***either*** that the product's risks

[25] Moreover, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under New York law. Thus, for the same reasons as stated above, Plaintiff need not prove his or her case in his or her complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was manufactured at this stage of the litigation. All plaintiff must do is allege facts that make it plausible that it is the case. Plaintiff has done so for the same reasons stated in Section V.A.2.a., *supra*.

outweighed its utility ***or*** that the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Am. Cyanamid Co.*, 155 N.J. at 570–71 (emphasis in the original). Thus, it is almost always that "the jury [i]s required to perform a risk-utility analysis." *Lewis v. Am. Cyanamid Co*., 155 N.J. at 560. And a jury's evaluation of of the risk-utility factors "may justify a conclusion that ***even though there is presently no alternative design*** which would make a product safer [liability may still be found]." *Smith v. Keller Ladder Co*., 275 N.J. Super. 280, 283-84 (N.J. App.Div. 1994) (emphasis added).

Even though not required under New Jersey law, as discussed, *see* Section V.A.2.b., *supra*, Plaintiff has pointed to such a feasible alternative design: the existence of "alternative safer products" when compared against Invokana, which is "more dangerous than an ordinary consumer would expect, and more dangerous than other risks associated with the other medications and similar drugs on the market to treat type 2 diabetes." Comp. ¶¶25, 51(b), (c).[26] But it is not only the existence of safer, alternative type 2 diabetes medications that form the basis for a design defect, it is also the insufficient and inadequately tested and labeled Invokana. Comp. ¶¶51(d), & (f). Defendants do not attempt to refute these allegations.

d. The failure to warn claim (Count 3) is plausibly pled

As noted at Section V.A.2.c., *supra*, weighing the adequacy of Defendants' warnings is not appropriate on a motion to dismiss. This is equally as true under New Jersey law as New York law. See *In re Ductile Iron Pipe Fittings ("DIPF") Direct Purchaser Antitrust Litig.*, No. CIV. 12-711, 2014 WL 3971620, at *6 (D.N.J. Aug. 13, 2014) ("In ruling on a motion to dismiss, the Court may not weigh evidence or otherwise decide which version of the facts is true.") (citing *Acevedo v. Monsignor Donovan High Sc*h., 420 F.Supp.2d 337, 342 (D.N.J.2006).) Countless New Jersey Courts have held the same in the context of pharmaceutical cases. *See, e.g., In re*

[26] Again, Defendants restate their confused plausibility versus particularity-level desired pleading standard under New Jersey law, just as they did under New York law. Thus, for the same reasons as stated above, Plaintiff need not prove their case in their complaint and answer propriety information necessarily only in Defendants' hands about "how" a drug was designed at this stage of the litigation. All Plaintiff must do is allege facts that make it plausible that it is the case. Plaintiff has done so for the same reasons stated in Section V.A.2.b., *supra*.

Reglan Litig., No. A-2014-13T4, 2014 WL 5840281, at *7 (N.J. Super. Ct. App. Div. Nov. 12, 2014), leave to *appeal granted*, 224 N.J. 278, 132 A.3d 422 (App. Div. 2015); *Kendall v. Hoffman-La Roche, Inc.*, 209 N.J. 173, 197, 36 A.3d 541, 556 (N.J. 2012). Thus, for the same reasons stated in Section V.A.2.c., *supra*, this Court should not dismiss Plaintiff's this claim.

e. Mr. Benjamin's express warranty claim (Count 4) is plausibly pled

Defendants argue that plaintiff failed to provide a pre-suit notice under New Jersey law of his express warranty claim. But because it is premature to determine if Plaintiff's express warranty claim should be analyzed under New York or New Jersey law (and because Defendants have made no attempt, as is their burden, to argue which should apply) the question of pre-suit notice under New Jersey Law (if even applicable) is premature. *See* Section III.

Defendants' remaining quarrels with Plaintiff's express warranty claim are the same as those outlined as to the New York claim: they want "more." But for the same reasons that Plaintiff's express warranty claim would survive under New York law, it survives under New Jersey law. *See* Section V.A.2.d.1.

4. Mr. Benjamin's Claim for Punitive Damages (Count 12) Survives

Generally, New Jersey allows for punitive damages in cases where "the product manufacturer knowingly withheld or misrepresented information required to be submitted under the agency's [FDA's] regulations, which information was material and relevant to the harm in question." N.J. Stat. Ann. § 2A:58C-5c. As Defendants point out, however, following *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), but, importantly, before *Wyeth v. Levine*, 555 U.S. 555, the New Jersey appellate decision held that punitive damages could not be sought under the facts of *McDarby v. Merck & Co.*, 949 A.2d 223, 275–76 (N.J. Super. Ct. App. Div. 2008). *Wyeth* held that federal law does not preempt state torts claims imposing liability on drug labeling that the FDA had previously approved because FDA's "changes being effected" (CBE) regulation permits unilateral labeling changes that improve drug safety. 555 U.S. at 568 (citing 21 CFR §§ 314.70(c)(6)(iii)(A), (C)). As such, the Supreme Court stated, "it has remained a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at

all times." 555 U.S. 555, 570–71. Thus, subsequent to *Wyeth*, this District and other districts across the nation have called *McDarby's* reasoning into question. "The vitality of *McDarby* was subsequently cast into some doubt by the Supreme Court's decision in *Wyeth.*" *Sullivan v. Novartis Pharms. Corp.*, 602 F. Supp. 2d 527, 534 n.8 (D.N.J. 2009). "The holding of *McDarby*, however, has been called into doubt by *Wyeth* … and *Forman v. Novartis Pharmaceuticals Corp*., 793 F.Supp.2d 598 (E.D.N.Y. 2011)" *Hill v. Novartis Pharm. Corp.*, No. 1:06-CV-00939-AWI, 2012 WL 967577, at *2 (E.D. Cal. Mar. 21, 2012) (same).

Timing is critical. Because *McDarby* preceded *Wyeth*, the *McDarby* court did not have the ability to consider the Supreme Court's determination that a drug manufacturer may change the label of brand-name drugs without prior FDA approval for reasons of safety. Thus, it is possible for a drug manufacturer to come to know of information that would call for an updated warning (i.e., knowingly withhold information from the FDA), but fail to update the labeling, thereby satisfying N.J. Stat. Ann. § 2A:58C-5c.

With respect to New York, Defendants only quarrel that punitive damages are a remedy, not an independent cause of action. But they have not stated, at all, why Plaintiffs should not be able to pursue such punitive damage as a matter of law given that Plaintiffs *have* included punitive damages in their prayer for relief in general, Compl. p. 40, as well as after each and every cause of action specifically. *See, e.g.*, Compl. p. 35 ("Plaintiff respectfully requests that this Court enter judgment in Plaintiff's favor for … punitive damages.") Thus, any determination on punitive damages under New York law is premature because Plaintiff have done exactly what Defendants demand: prayed for such relief. In any event, such a question is one for a jury under New York law.[27]

B. Mr. Benjamin's Design Defect-Based Claims Are Not Preempted By Federal Law

Invokana is a brand-name prescription drug for which there is currently no generic

[27] *Home Ins. Co. v. Am. Home Products Corp.*, 75 N.Y.2d 196, 204 (N.Y. 1990). ("[N]othing in New York law or public policy would preclude an award of punitive damages in a strict products case, where the theory of liability is failure to warn and where there is evidence that the failure was wanton or in conscious disregard of the rights of others.").

equivalent. Generally speaking, brand-name prescription drugs are regulated differently than generic prescription drugs. This is because it is the brand-name manufacturer that seeks approval from the FDA to market the drug and which is in possession of clinical testing data and safety information, conducted and collected both before and after a drug comes to market. By contrast, generic manufacturers do not generally conduct safety testing. Rather they are merely copying an existing formulation for a brand name drug. Indeed, that is why generic manufacturers must conform their product labels with those of the brand name manufacturers. 57 Fed.Reg. 17961 (1992) ("[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval"). Courts have recognized this distinction and have generally ruled that state claims for failure to warn (and in some cases, design defect) against *generic* manufacturers are preempted. *See, e.g.*, *In re Darvocet, Darvon & Propoxyphene Products Liab. Litig.*, No. 2:11-MD-2226-DCR, 2012 WL 2457825, at *1 (E.D. Ky. June 22, 2012), *aff'd sub nom. In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917 (6th Cir. 2014) (dismissing all generic propoxyphene cases in a MDL). Courts, however, have not typically extended this protection to brand name prescription drug manufacturers.

Despite the Supreme Court precedent recognizing this distinction, Defendants argue that their *brand*-name drug should still be protected from liability under a theory of *conflict* preemption theory because it is the FDA, not the Defendants, that approved its drug design, composition, and dosage. Def. Mot. at 21-27. While that may be true, it is the Defendants that submitted their drug for approval in the first instance. It is the Defendants that initially designed and developed Invokana, and submitted proposed labeling for the drug. Therein lies Defendants liability. Further, absent discovery regarding the regulatory submissions made by Defendants, as well as any communications between Defendants and the FDA, it is not what information was provided to the FDA regarding the safety of the drug. Thus, as a practical matter, any consideration of conflict preemption would be premature.

Nevertheless, Defendants cite to three Supreme Court cases that they claim require

dismissal with prejudice. None of the three Supreme Court cases Defendants cite, as discussed below, at issue are on point, and certainly none of them mandate dismissal of Plaintiff's claims.

First, *Wyeth* held that a brand-name drug manufacturer can be held liable for failure to warn claims because regulations allow a manufacturer to implement label changes with the FDA's prior approval. Thus, the Court stated:

> Wyeth has not persuaded us that failure-to-warn claims like Levine's obstruct the federal regulation of drug labeling. Congress has repeatedly declined to pre-empt state law, and the FDA's recently adopted position that state tort suits interfere with its statutory mandate is entitled to no weight. Although we recognize that some state-law claims might well frustrate the achievement of congressional objectives, this is not such a case. . . . We conclude that it is not impossible for Wyeth to comply with its state-and federal-law obligations and that Levine's common-law claims do not stand as an obstacle to the accomplishment of Congress' purposes in the FDCA.

Wyeth v. Levine, 555 U.S. 555, 581 (2009).

The second case cited by Defendants, the *Mensing* case, reiterates *Wyeth* but instead does preempt failure-to-warn claims when a ***generic***, and not brand-name, drug is at issue.

> We recognize that from the perspective of [plaintiffs] Mensing and Demahy, finding pre-emption here but not in *Wyeth* makes little sense. Had Mensing and Demahy taken Reglan, the brand-name drug prescribed by their doctors, Wyeth would control and their lawsuits would not be pre-empted. But because pharmacists, acting in full accord with state law, *substituted generic metoclopramide* instead, federal law pre-empts these lawsuits.

PLIVA, Inc. v. Mensing, 564 U.S. 604, 625 (2011) (emphasis added). The Plaintiff in this case took brand name Invokana, not a generic substitute—because no such generic drug exists. Compl. ¶8.

Finally, the third case cited by the Defendants, *Bartlett*, simply extended *Mensing* such that claims involving ***generic*** drugs applies to design-defect claims (and not only failure to warn claims as were at issue in *Mensing*). "As *PLIVA* made clear, federal law prevents *generic drug manufacturers* from changing their labels." *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2476 (2013) (emphasis added). Thus, these cases provide no basis for dismissal of a brand-name drug.

The Defendants cite several lower court decisions in jurisdictions not binding on this Court that extend the *Mensing* and *Bartlett* opinions beyond the realm of generic drugs—but

mostly applying preemption *outside the context of pharmaceutical drugs*. Def. Mot. at 24-25.

For example, Defendants cite to the Third Circuit case *Sikkelee v. Precision Airmotive Corp.*, 822 F.3d 680 (3d Cir. 2016). That citation is odd for multiple reasons. First, *Sikkelee* held that the Federal Aviation Act of 1994 (hardly a pharmaceutical case) does *not* act to preempt state-law based aircraft product liability claims. *Id.* at *683. The Third Circuit so held because of the "presumption against preemption [under which] Congress must express its clear and manifest intent to preempt an entire field of state law." *Id*. Second, the Third Circuit expressly states the opposite of the proposition for which Defendants say it stands for.

> In a series of recent preemption cases, the [Supreme] Court has **distinguished between brand-name drugs and their generic equivalents**, determining that at least some state law tort claims may be brought against brand-name drug companies because such companies have the ability to make some unilateral changes to their labels without additional regulatory preapproval, but such claims against generic drug manufacturers cannot survive a conflict preemption analysis because the generic manufacturers are bound by federal law to directly mimic their brand-name counterparts.

Id. at *703 (emphasis added).

As the Third Circuit boiled down so well, generic drug claims of all types usually fail, but branded-name drugs (like Invokana) are not preempted. Two sister courts in this Circuit agree, of course. "The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs. I conclude that its preemption cases do not extend to the manufacturers of these products." *Brown v. Johnson & Johnson*, 64 F.Supp.3d 717, 721 (E.D. Pa. 2014).

> [T]he same federal regulations that apply to generic manufacturers do not necessarily apply to brand-name manufacturers, such as the defendants. … This explains why the failure-to-warn claim brought against a generic drug manufacturer in PLIVA was preempted but failure-to-warn claim brought against the brand-name manufacturer in *Wyeth v. Levine* was not. … Following from this logic, I find that *Bartlett*—a case involving a generic manufacturer and following *PLIVA v. Messing*—does not apply to the plaintiff's design defect claim against a brand-name manufacturer. Under the dictates of *Wyeth v. Levine*, preemption is not warranted.

Terry v. McNeil-PPC, Inc., (In re Tylenol (Acetaminophen) Mktg.), No. 2436, 2015 WL 7075949, at *21–22 (E.D. Pa. Nov. 13, 2015).

The outlier cases cited by Defendants cannot be reconciled with the explicit language in *Mensing* and *Bartlett* and should be disregarded by the Court. As one district court noted about the rationale espoused by Defendants by the outside-of-this-circuit cases they cite, "[i]f this is the correct interpretation of *Bartlett*, then it appears virtually all design defect cases against generic and brand-name prescription drug manufacturers alike would be preempted." *Trahan v. Sandoz, Inc*., No. 3:13-CV-350-J-34MCR, 2015 WL 2365502, at *6 (M.D. Fla. Mar. 26, 2015). Defendants' interpretation of the law of federal preemption cannot be (and is not) correct.

C. All of Mr. Benjamin's Claims against Johnson & Johnson Remain Valid

As noted above, *see Section* V.A.1., *supra*, Johnson & Johnson had direct involvement in the development, sale, and marketing of Invokana. Even if this Court is not inclined to judicially notice the multitude of types and sources of materials supporting J&J's awareness of and participation in the development and marketing of Invokana, this Court should *still* allow claims against J&J to proceed at this stage in the litigation.

Plaintiff's claims allege that J&J, *inter alia*, marketed Invokana. Compl ¶10. Based on far less, indeed mere knowledge of a subsidiary's wrongdoing, the Northern District of Texas allowed such claims to proceed against J&J with respect to its medical device wholly-owned subsidiary, DePuy. *Lay v. DePuy Orthopaedics, Inc.* (In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.), No. 3:11-MD-2244-K, 2014 WL 3557392 (N.D. Tex. July 18, 2014). There, the court reasoned that Restatement (Second) of Torts §876(b) applies because J&J "is subject to liability for harm to a third person resulting from the tortious conduct of another if [it] knows that the other's [here, Janssen's] conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other so to conduct himself." *Id.* at *3. The case had already survived on a motion to dismiss on this ground and discovery revealed that the "evidence ... raises fact issues that the Johnson & Johnson Companies knew that DePuy was engaged in the manufacture and marketing of a defective product and that they provided assistance to DePuy in marketing that product." *Id.* That knowledge included, among other things, that its subsidiary was facing manufacturing problems with its hip components, which J&J continued to exercise control over

marketing and advertising, that the J&J name was placed on packaging of the device, and that the J&J name was used in doctor marketing efforts. *Id.* at *3.

Both New Jersey and New York recognize the Restatement (Second) of Torts §876(b). "The Supreme Court of New Jersey adopted the Restatement (Second) of Torts § 876(b) standard" *Shah v. Wisconsin*, No. CIV. 11-0419, 2011 WL 5192127, at *5 (D.N.J. Oct. 31, 2011) (citing *Tarr v. Ciasulli*, 181 N.J. 70, 853 A.2d 921, 928 (N.J. 2004)); *see also Failla v. City of Passaic*, 146 F.3d 149, 158 (3d Cir. 1998); *Hurley v. Atlantic City Police Dep't*, 174 F.3d 95, 129 (3d Cir. 1999); *Bondi v. Citigroup, Inc.*, No. L-10902-04, 2005 N.J. Super. Unpub. LEXIS 790, 2005 WL 975856, at *17 (N.J. Super Ct. Law Div. Feb. 28, 2005) (stating that courts in this circuit and in New Jersey recognize "civil aiding and abetting liability" as described in the Restatement (Second) of Torts § 876(b)). New York has similarly adopted §876(b). *See, e.g., Miele v. Am. Tobacco Co.*, 2 A.D.3d 799, 805 (2nd Dept. N.Y. 2003) ("the concerted action theory of liability for injury to a third party will attach when one knows that another's conduct constitutes a breach of duty and gives substantial assistance or encouragement to the other").

The facts alleged and/or judicially noticeable here support a claim under the Restatement (Second) of Torts §876(b). As noted above, this Court can take judicial notice of the fact that J&J: 1) directed the physical labeling of Invokana, 2) published media information about Invokana's method of action, 3) announced to its shareholders its hopes for an approval of Invokana in 2012, 4) shared executives between J&J and Janssen, and 5) J&J's consumer brand director was (and remains) in charge of Invokana's marketing. Any one of these facts could lead a reasonable juror to believe that J&J's conduct constitutes a breach of duty and gives substantial assistance or encouragement to Janssen's conduct.

Moreover, Plaintiff's design defect does not call for the Defendant's to reformulate Invokana *now*, it is a claim that they should not have submitted the formulation (i.e., its design) in the first instance for approval. In other words, it is incumbent upon the drug manufacturer to make sure the drug is safe at all times – including the time the drug is first brought to market.

V. CONCLUSION

Plaintiff's complaint meets the applicable pleading standards. As a result, Defendants' motion to dismiss should be denied in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

It is hereby certified that a true copy of the foregoing was served electronically via the Court's electronic filing system on the 15th day of August 2016, upon all counsel of record.

Dated: August 15, 2016

/s/ Christopher A. Seeger
Christopher A. Seeger